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Introduction to Risk Assessment for Risk Managers and New Risk Assessors

RISK ASSESSMENT TRAINING AND EXPERIENCE
Basics of Risk Assessment 101

Office of Research and Development
National Center for Environmental Assessment

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Introduction to Risk Assessment for Risk Managers and New Risk Assessors

- The purpose of this course is to:
  - Teach some fundamental concepts and terminology associated with risk assessment,
  - Inform how the risk assessment process is related to and informs risk management

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Why should you know about risk assessment?

"Risk assessment has become **a dominant public-policy tool** for informing risk managers and the public about the different policy options for protecting public health and the environment (From "Science and Decisions, National Academy of Sciences, 2009).

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The National Research Council is the primary advisor to the US Federal government on risk assessment

- National Research Council (NRC) publications on risk assessment
  - 1983: *Managing the Process* – the "Red Book"
  - 1989: *Improving Risk Communication*
  - 1994: *Science and Judgment* – the "Blue Book"
  - 1996: *Understanding Risk*
  - 2007: *Toxicity Testing in the 21st Century*
  - 2008: *Phthalates and Cumulative Risk Assessment*
  - 2009: *Science and Decisions* – the "Silver Book"

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Who else uses risk assessment?

Just about everybody.

Federal Agencies

ATSDR

OSHA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FDA

NIOSH

State Agencies

Office of Environmental Health Hazard Assessment

TCEQ

International Organizations

World Health Organization

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Definitions

Risk is the chance of harmful effects to human health or to ecological systems resulting from changes in the environment.

Risk assessment is a scientific process to logically and consistently organize information, and characterize risk.

Risk management is the process of determining how to protect public health and the environment.

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Risk Assessment Has Four Components.

- **Hazard Identification**
- **Dose-response Assessment**
- **Exposure Assessment**
- **Risk Characterization**

Evaluation of scientific information on:

- the hazardous (potentially dangerous) properties of environmental agents,
- the dose-response relationship, and
- the extent of exposure to those agents.

The product of the risk assessment is a statement regarding the probability that populations or individuals so exposed will be harmed and to what degree.

From EPA's Glossary of IRIS Terms

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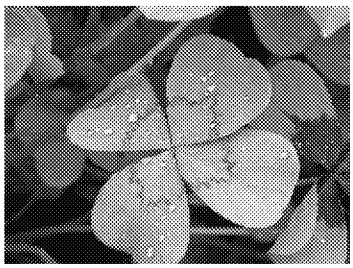
But you're in luck???

There is a module for each of the four components designed just or you.



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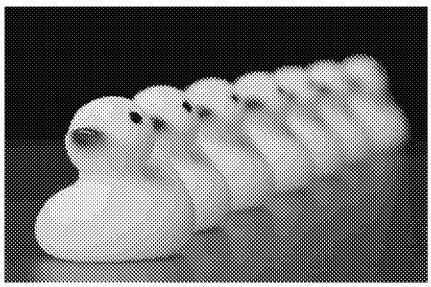
BUT before you even start a risk assessment you need to get ready



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Planning and Scoping

Identify the Problem

- Where does the problem exist?
- What exposures are likely (magnitude, duration, frequency)
- Who or what is affected?
- What causal agents should be considered?
- What are the system boundaries?
- What are risk management needs?
- What are stakeholder needs?

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Involve Stakeholders

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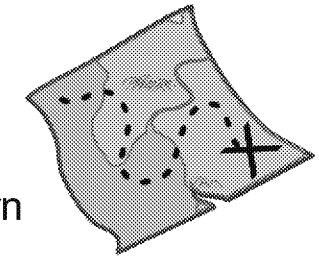
Why Plan, Scope and Involve Stakeholders?



- If you don't plan, the assessment may not actually address the problem of concern
- Stakeholders help raise important issues
- In a democratic society, stakeholder should feel like the process is fair, reasonable, and their concern are heard

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And after you're done with risk assessment remember .....

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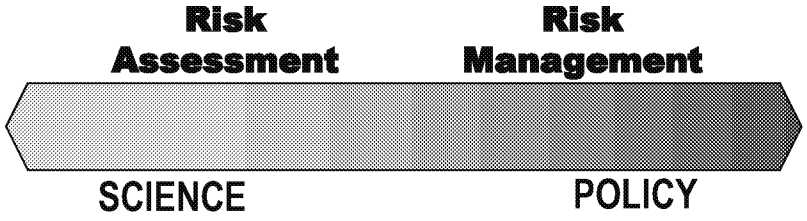
Risk Assessment and Risk Management Are Interrelated



- Risk assessors and risk managers need to have a good sense of when a decision is scientific judgment versus when it is a policy decision informed by science.
- Opinions vary on how separated risk assessment and risk management should be.
- The most current frameworks recommend an iterative process.
- Transparency is key.

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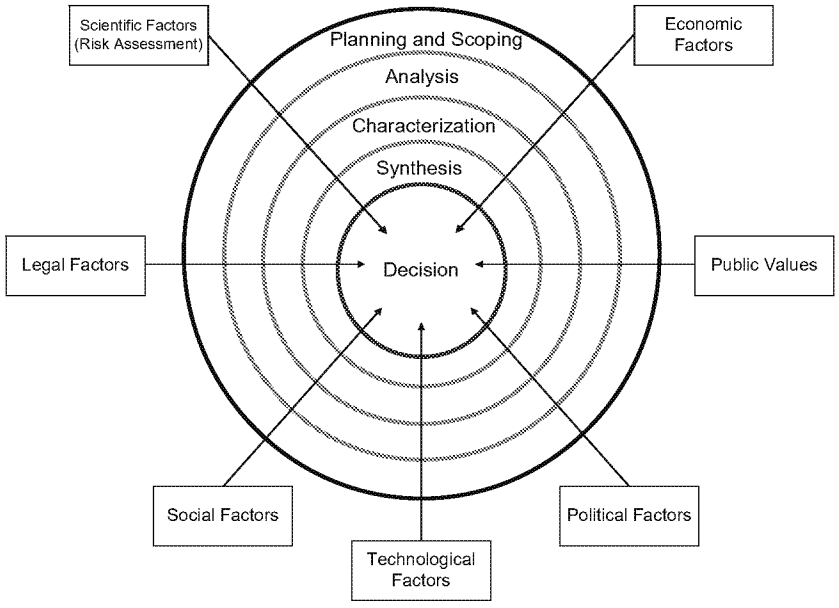
Science is one of many factors a risk mangers needs to consider



Source: EPA's Risk Characterization Handbook (2000)

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Examples of Two Common Risk Management Options

Standards	Guidelines
Relatively few	Numerous
Mandated by statute and legally enforceable	Not legally enforceable
Rigid development process	Flexible development process
Developed by government agencies specified in statutes	Developed by many types of entity
Intended to protect health and the environment, but balances other considerations	Intended to protect human health and the environment

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Examples of Exposure Standards

Medium	Standard	Regulated Contaminants	Regulatory Authority
Air	National Ambient Air Quality Standards (**NAAQS**)	6 Criteria Pollutants in ambient air	EPA, as mandated by the Clean Air Act
	Permissible Exposure Limits (**PELs**)	~500 contaminants in workplace air	OSHA, as mandated by the Occupational Safety and Health Act
Water	Maximum Contaminant Levels (**MCLs**)	90 chemical, microbiological, radiological, and physical contaminants in drinking water	EPA, as mandated by the Safe Drinking Water Act
Food	Maximum Residue Limits (**MRLs**)	Hundreds of pesticide chemicals in food and feed commodities	EPA, as mandated by the Federal Food, Drug, and Cosmetics Act, as amended by the Food Quality Protection Act

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Summary

- There is a well define process for risk assessment with lots of guidance from the science community
- Risk assessors and risk mangers need to effectively communicate the environmental problem of concern, and design the type of assessment that will help us understand that problem
- Stakeholders are critical part of that process
- Science is not the only thing risk managers need to consider
- Science can support lots of different kinds of risk management options